

**Introduced by Senator Figueroa**

February 17, 2004

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An act to amend Sections 4160, 4163, 4164, 4165, and 4166 of, to repeal Section 4162 of, and to repeal and add Section 4161 of, the Business and Professions Code, relating to drugs.

**LEGISLATIVE COUNSEL'S DIGEST**

SB 1307, as introduced, Figueroa. Wholesalers and manufacturers of dangerous drugs and devices.

Existing law, the Pharmacy Law, provides for the licensing and regulation of wholesalers of dangerous drugs or dangerous devices by the Pharmacy Board. Existing law makes the violation of Pharmacy Law a crime. Existing law prohibits a person acting as a wholesaler of dangerous drugs or devices without a license.

This bill would require dangerous drugs or dangerous devices to be acquired from a person authorized by law to possess or furnish them. The bill would exempt a licensed drug manufacturer that only ship drugs of its own manufacture from the provisions governing wholesalers, except for the prohibition against furnishing dangerous drugs or devices to an unauthorized person.

Existing law imposes certain licensing and registration requirements on out-of-state manufacturers and wholesalers doing business in this state, and on their principals.

This bill would delete these requirements. The bill would make a wholesaler located outside the state that ships, mails, or delivers dangerous drugs or dangerous devices into this state a nonresident wholesaler. The bill would require a nonresident wholesaler to meet specified licensing and reporting requirements, to comply with lawful directions and requests for information, to maintain a record in readily



retrievable form of dangerous drugs or dangerous devices sold, traded, or transferred to persons in this state, and to designate an exemptee-in-charge to be responsible for compliance with laws governing wholesalers.

Existing law requires any manufacturer who sells or transfers a dangerous drug or dangerous device into this state or who receives a dangerous drug or dangerous device from a person in this state to, upon request, furnish an authorized officer of the law with all records or other documentation of that sale or transfer. Existing law makes a manufacturer who fails or refuses to comply with that request subject to a citation and a fine, an order of abatement, or both.

This bill would instead apply these provisions to a wholesaler licensed by the board. The bill would delete the provision that makes the failure or refusal to comply with a request subject to a citation and a fine, an order of abatement, or both.

Because a violation of the requirements and prohibitions created by this bill would be a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

*The people of the State of California do enact as follows:*

1 SECTION 1. Section 4160 of the Business and Professions  
2 Code is amended to read:

3 4160. (a) No person shall act as a wholesaler of any  
4 dangerous drug or dangerous device unless he or she has obtained  
5 a license from the board. ~~Upon~~

6 (b) *Upon* approval by the board and the payment of the required  
7 fee, the board shall issue a license to the applicant.

8 ~~(b) No selling or distribution outlet, located in this state, of any~~  
9 ~~out-of-state manufacturer, that has not obtained a license from the~~  
10 ~~board, that sells or distributes only the dangerous drugs or the~~  
11 ~~dangerous devices of that manufacturer, shall sell or distribute any~~

~~dangerous drug or dangerous device in this state without obtaining a wholesaler's license from the board.~~

(c) A separate license shall be required for each place of business owned or operated by a wholesaler. Each license shall be renewed annually and shall not be transferable.

(d) The board shall not issue or renew a wholesaler license until the wholesaler designates an exemptee-in-charge and notifies the board in writing of the identity and license number of that exemptee. The exemptee-in-charge shall be responsible for the wholesaler's compliance with state and federal laws governing wholesalers. Each wholesaler shall designate, and notify the board of, a new exemptee-in-charge within 30 days of the date that the prior exemptee-in-charge ceases to be exemptee-in-charge. A pharmacist may be designated as the exemptee-in-charge.

(e) For purposes of this section, "exemptee-in-charge" means a person granted a certificate of exemption pursuant to Section 4053, or a registered pharmacist, who is the supervisor or manager of the facility.

(f) *A drug manufacturer licensed pursuant to Section 111615 of the Health and Safety Code that only ships drugs of its own manufacture is exempt from this section.*

SEC. 2. Section 4161 of the Business and Professions Code is repealed.

~~4161. (a) No person shall act as an out-of-state manufacturer or wholesaler of dangerous drugs or dangerous devices doing business in this state who has not obtained an out-of-state dangerous drug or dangerous device distributor's license from the board. Persons not located in this state selling or distributing dangerous drugs or dangerous devices in this state only through a licensed wholesaler are not required to be licensed as an out-of-state manufacturer or wholesaler or have an out-of-state dangerous drug or dangerous device distributor's license.~~

~~(b) Applications for an out-of-state dangerous drug or dangerous device distributor's license shall be made on a form furnished by the board. The board may require any information as the board deems is reasonably necessary to carry out the purposes of the section. The license shall be renewed annually.~~

~~(c) The Legislature, by enacting this section, does not intend a license issued to any out-of-state manufacturer or wholesaler pursuant to this section to change or affect the tax liability imposed~~

1 ~~by Chapter 3 (commencing with Section 23501) of Part 11 of~~  
2 ~~Division 2 of the Revenue and Taxation Code on any out-of-state~~  
3 ~~manufacturer or wholesaler.~~

4 ~~(d) The Legislature, by enacting this section, does not intend a~~  
5 ~~license issued to any out-of-state manufacturer or wholesaler~~  
6 ~~pursuant to this section to serve as any evidence that the~~  
7 ~~out-of-state manufacturer or wholesaler is doing business within~~  
8 ~~this state.~~

9 SEC. 3. Section 4161 is added to the Business and Professions  
10 Code, to read:

11 4161. (a) A wholesaler located outside this state that ships,  
12 mails, or delivers dangerous drugs or dangerous devices into this  
13 state shall be considered a nonresident wholesaler for purposes of  
14 this chapter.

15 (b) A nonresident wholesaler shall be licensed by the board.

16 (c) A separate license shall be required for each place of  
17 business owned or operated by a nonresident wholesaler. Each  
18 license shall be renewed annually and shall not be transferable.

19 (d) A nonresident wholesaler shall disclose to the board the  
20 names, locations, and titles of each of the following:

21 (1) Its agent for service of process in this state.

22 (2) Principal corporate officers, as specified by the board.

23 (3) General partners, as specified by the board.

24 (e) A report containing the information in subdivision (d) shall  
25 be made within 30 days of any change of office.

26 (f) A nonresident wholesaler shall comply with all lawful  
27 directions and requests for information from the regulatory or  
28 licensing agency of the state in which it is licensed, as well as with  
29 all requests for information made by the board pursuant to this  
30 section.

31 (g) A nonresident wholesaler shall maintain a record of  
32 dangerous drugs and dangerous devices sold, traded, or transferred  
33 to persons in this state, and the record shall be in a readily  
34 retrievable form.

35 (h) A nonresident wholesaler shall at all times maintain a valid,  
36 unexpired license, permit, or registration to conduct the business  
37 of the wholesaler in compliance with the laws of the state in which  
38 it is a resident. An application for a nonresident wholesaler license  
39 in this state shall include a license verification from the licensing  
40 authority in the applicant's state of residence.

(i) The board shall not issue or renew a nonresident wholesaler license until the nonresident wholesaler designates an exemptee-in-charge and notifies the board in writing of the identity and license number of the exemptee-in-charge.

(j) The exemptee-in-charge shall be responsible for the nonresident wholesaler's compliance with state and federal laws governing wholesalers. Each nonresident wholesaler shall designate and notify the board of a new exemptee-in-charge within 30 days of the date that the prior exemptee-in-charge ceases to be the exemptee-in-charge.

(k) For purposes of this section, "exemptee-in-charge" means a person granted a certificate of exemption pursuant to Section 4053 or a registered pharmacist who is the supervisor or manager of the facility.

(l) The registration fee shall be the fee specified in subdivision (f) of Section 4400.

SEC. 4. Section 4162 of the Business and Professions Code is repealed.

~~4162. (a) No person acting as principal or agent for any out-of-state manufacturer, wholesaler, or pharmacy who has not obtained a license from the board, and who sells or distributes dangerous drugs or dangerous devices in this state that are not obtained through a wholesaler who has obtained a license, pursuant to this chapter, or that are not obtained through a selling or distribution outlet of an out-of-state manufacturer that is licensed as a wholesaler, pursuant to this chapter, shall conduct the business of selling or distributing dangerous drugs or dangerous devices within this state without registering with the board.~~

~~(b) Registration of persons under this section shall be made on a form furnished by the board. The board may require any information as the board deems reasonably necessary to carry out the purposes of this section, including, but not limited to, the name and address of the registrant and the name and address of the manufacturer whose dangerous drugs or dangerous devices he or she is selling or distributing.~~

~~(c) The board may deny, revoke, or suspend the person's registration for any violation of this chapter or for any violation of Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code. The board may deny, revoke, or suspend the person's registration if the manufacturer, whose dangerous~~

~~1 drugs or dangerous devices he or she is selling or distributing,  
2 violates any provision of this chapter or any provision of Part 5  
3 (commencing with Section 109875) of Division 104 of the Health  
4 and Safety Code. The registration shall be renewed annually.~~

5 SEC. 5. Section 4163 of the Business and Professions Code  
6 is amended to read:

7 4163. (a) No manufacturer or wholesaler shall furnish any  
8 dangerous drugs or dangerous devices to any unauthorized  
9 persons.

10 (b) *Dangerous drugs or dangerous devices shall be acquired*  
11 *from a person authorized by law to possess or furnish dangerous*  
12 *drugs or dangerous devices.*

13 SEC. 6. Section 4164 of the Business and Professions Code  
14 is amended to read:

15 4164. All wholesalers licensed by the board ~~and all~~  
16 ~~manufacturers who~~ *that* distribute controlled substances,  
17 dangerous drugs, or dangerous devices within or into this state  
18 shall report to the board all sales of dangerous drugs and controlled  
19 substances that are subject to abuse, as determined by the board.

20 SEC. 7. Section 4165 of the Business and Professions Code  
21 is amended to read:

22 4165. ~~(a) Any manufacturer~~ *wholesaler licensed by the*  
23 *board* who sells or transfers any dangerous drug or dangerous  
24 device into this state or who receives, by sale or otherwise, any  
25 dangerous drug or dangerous device from any person in this state  
26 shall, on request, furnish an authorized officer of the law with all  
27 records or other documentation of that sale or transfer.

28 ~~(b) Any manufacturer who fails within a reasonable time, or~~  
29 ~~refuses, to comply with subdivision (a), shall be subject to citation~~  
30 ~~and a fine, an order of abatement, or both, pursuant to Section~~  
31 ~~125.9 and any regulations adopted by the board, in addition to any~~  
32 ~~other remedy provided by law.~~

33 SEC. 8. Section 4166 of the Business and Professions Code  
34 is amended to read:

35 4166. (a) Any wholesaler ~~or other distributor~~ that uses the  
36 services of any carrier, including, but not limited to, the United  
37 States Postal Service or any common carrier, shall be liable for the  
38 security and integrity of any dangerous drugs or dangerous devices  
39 through that carrier until the drugs or devices are delivered to the  
40 transferee at its board-licensed premises.

1 (b) Nothing in this section is intended to affect the liability of  
2 a wholesaler ~~or other distributor~~ for dangerous drugs or dangerous  
3 devices after their delivery to the transferee.

4 SEC. 9. No reimbursement is required by this act pursuant to  
5 Section 6 of Article XIII B of the California Constitution because  
6 the only costs that may be incurred by a local agency or school  
7 district will be incurred because this act creates a new crime or  
8 infraction, eliminates a crime or infraction, or changes the penalty  
9 for a crime or infraction, within the meaning of Section 17556 of  
10 the Government Code, or changes the definition of a crime within  
11 the meaning of Section 6 of Article XIII B of the California  
12 Constitution.

